1634

Docket No. 65504-A/JPW/FHB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Shlomit Gilad and Rami Skaliter
U.S. Serial No.	:	09/810,993 Examiner: J. Goldberg
Filed	:	March 16, 2001 Group Art Unit: 1634
For	:	ATM MUTATIONS IN BREAST CANCER

1185 Avenue of the Americas
New York, New York 10036
July 23, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO JUNE 26, 2002 OFFICE ACTION

This Communication is submitted in response to the Office Action issued by the U.S. Patent and Trademark Office on June 26, 2003 in connection with the above-identified application. A response to the June 26, 2003 Office Action is due July 26, 2003. Accordingly, this Response is being timely filed.

In the June 26, 2003 Office Action, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I-II:

I. Group I, claims 1-6 and 11-22, drawn to methods of determining if individuals have a predisposition for developing breast cancer by detecting a mutation in the ATM gene, classified in class 435, subclass 6;

II. Group II, claims 7-10, drawn to an isolated cDNA, classified in class 536, subclass 23.1;

The Examiner asserted at the inventions of Groups I and II are related as product and process of use. Inventions in this relationship can be shown to be distinct if (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product as set our in MPEP §806.05(h). The Examiner alleged that the nucleic acid of Group II may be used in methods of analyzing sporadic T-cell leukemia, methods of purification, isolation, apatmer screening methods, hybridization assays, and antisense methods. For these reasons, the Examiner asserted that these Groups are patentably distinct.

In response, applicants hereby elect, with traverse, the claims of Group I, specifically claims 1-6 and 11-22.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

First, the inventions of the cited Groups are not independent. Under MPEP §802.01, "independent" means there is no disclosed relationship between the subjects disclosed. Group I claims a method for testing a subject to determine if the subject has a predisposition for developing breast cancer by detecting a mutation in the ATM gene. Group II claims an isolated cDNA and a marker comprising the isolated cDNA. Groups I and II are necessarily related because the marker of Group II is directed towards the same ATM mutations as those being detected as part of the method of Group I. Therefore, the marker of Group II is necessary for the detection step of the method of Group I. The

Applicants therefore maintain that the cited Groups are not "independent".

Finally, under MPEP § 803, there are two criteria for a proper restriction requirement: 1) the invention must be independent or distinct, and 2) there must be a serious burden on the Examiner if restriction is required. MPEP §803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required between Groups I-II because a search of the prior art relevant to any of the claims of any of the Groups would necessarily turn up the prior art relevant to the claims of the remaining Groups, and *vice versa* because both of the groups are components of the process of determining if individuals have a predisposition for developing breast cancer by detecting a mutation in the ATM gene. Since there is no burden on the Examiner to examine Groups I-II together in the subject application, it is submitted that the Examiner must examine the entire application on the merits.

In the June 26, 2003 Office Action, the Examiner further required restriction to a single nucleic acid sequence or, where necessary, a single combination of sequences.

The Examiner alleged that each marker/sequence is patentably distinct because nucleotide sequence encoding different proteins are structurally distinct chemical compounds and are unrelated to one another.

In response, applicants hereby elect, with traverse, mutation

2119 T->C. For those claims which require two or more mutations, applicants hereby elect, with traverse, mutation 2119 T->C in combination with at least one other mutation from Table 4. Applicants note that this same election was made in the Amendment in Response to August 30, 2002 Office Action and Petition for Three Month Extension of Time filed with the U.S. Patent Office on December 30, 2002.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

The Examiner alleged that each marker/sequence is patentably distinct because they are unrelated sequences and that the sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. Applicants contend that this is not correct, since the claims are all directed to detecting single mutations in the same gene for the same disease. Applicants therefore maintain that the pending claims constitute a single invention.

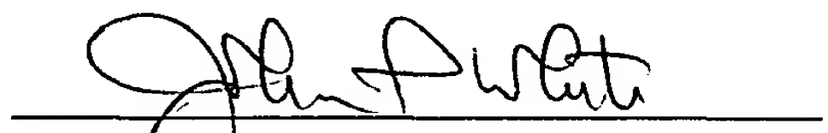
SUMMARY

In view of the foregoing, applicants maintain that the June 26, 2003 restriction requirement is not proper under 35 U.S.C. § 121 and respectfully request that the Examiner reconsider and withdraw the requirement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

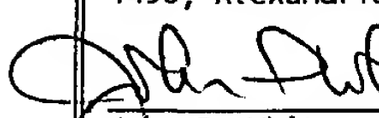
No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



7/23/03

John P. White Date
Reg. No. 28,678